

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problems Mailbox.**



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11)

EP 1 110 580 A2

(12)

## EUROPEAN PATENT APPLICATION

(43) Date of publication:  
27.06.2001 Bulletin 2001/26

(51) Int Cl.7: A61N 1/368

(21) Application number: 00310457.7

(22) Date of filing: 24.11.2000

(84) Designated Contracting States:  
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU  
MC NL PT SE TR  
Designated Extension States:  
AL LT LV MK RO SI

• Bornzin, Gene A.  
Simi Valley, CA 93065 (US)  
• Poore, John W.  
South Pasadena, CA 91030 (US)  
• Kurschinski, Douglas T.  
Valencia, CA 91354 (US)

(30) Priority: 23.12.1999 US 471788

(71) Applicant: PACESETTER, INC.  
Sylmar, CA 91392-9221 (US)

(74) Representative: Roberts, Gwilym Vaughan et al  
KILBURN & STRODE,  
20 Red Lion Street  
London WC1R 4PJ (GB)

(72) Inventors:  
• Florio, Joseph J.  
La Canada, CA 91011 (US)

(54) **Methods and apparatus for overdrive pacing heart tissue using an implantable cardiac stimulation device**

(57) Techniques are described for overdrive pacing the heart 12 using a pacemaker 10 wherein the overdrive pacing rate only increases when at least two intrinsic beats are detected within a determined search period. In one specific technique, an increase in the pacing rate occurs only if two P-waves are detected within X cardiac cycles. In another specific technique, the overdrive pacing rate is increased only if at least two P-waves are detected within a block of N cardiac cycles. In both techniques, the overdrive pacing rate is decreased if no increase has occurred in the last Z cardiac cycles. By increasing the overdrive pacing rate only in response to detection of at least two P-waves within a determined number of cardiac cycles, an excessively high overdrive pacing rate is avoided. Other techniques are described for adaptively adjusting overdrive pacing parameters so as to achieve a determined target degree of pacing of, for example, 95% paced beats. By adaptively adjusting overdrive parameters to maintain a target degree of pacing, the average overdrive pacing rate is minimised while still maintaining a high number of paced beats, thereby reducing the risk of a tachyarrhythmia occurring within the patient.

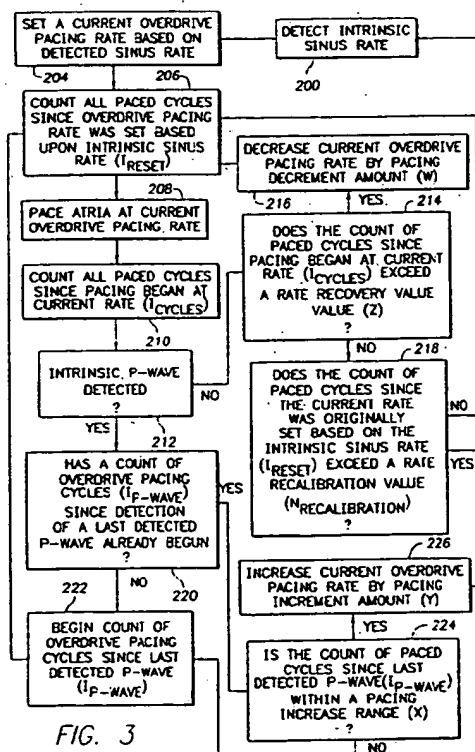


FIG. 3

EP 1 110 580 A2

## Description

[0001] The invention generally relates to implantable cardiac stimulation devices such as pacemakers, and in particular, to techniques for overdrive pacing heart tissue to prevent or terminate dysrhythmia.

[0002] A dysrhythmia is an abnormal heart beat pattern. One example of a dysrhythmia is a bradycardia wherein the heart beats at an abnormally slow rate or wherein significant pauses occur between consecutive beats. Other examples of dysrhythmias include tachyarrhythmias wherein the heart beats at an abnormally fast rate. With atrial tachycardia, the atria of the heart beat abnormally fast. With ventricular tachycardia, the ventricles of the heart beat abnormally fast. Though often unpleasant for the patient, a tachycardia is typically not fatal. However, some tachycardias, particularly ventricular tachycardia, can trigger ventricular fibrillation wherein the heart beats chaotically such that there is little or no net flow of blood from the heart to the brain and other organs. Ventricular tachycardia, if not terminated, is fatal. Hence, it is highly desirable to prevent or terminate dysrhythmias, particularly ventricular tachycardias.

[0003] One technique for preventing or terminating dysrhythmias is to overdrive pace the heart wherein an implantable cardiac stimulation device, such as a pacemaker or implantable cardioverter defibrillator (ICD), applies electrical pacing pulses to the heart at a rate somewhat faster than the intrinsic heart rate of the patient. For bradycardia, the cardiac stimulation device may be programmed to artificially pace the heart at a rate of 60 to 80 pulses per minute (ppm) to thereby prevent the heart from beating too slow and to eliminate any long pauses between heart beats. To prevent tachyarrhythmias from occurring, the cardiac stimulation device artificially paces the heart at a rate of at least five to ten pulses per minute faster than the intrinsic tachyarrhythmia heart rate of the patient. In other words, a slight artificial tachycardia is induced and maintained in an effort to prevent an actual tachycardia from arising. If an actual tachycardia occurs, such as a supraventricular tachycardia (SVT) wherein the heart may begin beating suddenly at 150 beats per minute or more, the cardiac stimulation device senses tachycardia and immediately begins pacing at a rate of at least five to ten pulses per minute (ppm) faster than the tachycardia and then slowly decreases the pacing rate in an effort to slowly reduce the heart rate back to a normal resting rate, thereby terminating the tachycardia.

[0004] It is believed that overdrive pacing is effective for at least some patients for preventing or terminating the onset of an actual tachycardia for the following reasons. A normal, healthy heart beats only in response to electrical pulses generated from a portion of the heart referred to as the sinus node. The sinus node pulses are conducted to the various atria and ventricles of the heart via certain, normal conduction pathways. In some

patients, however, additional portions of the heart also generate electrical pulses referred to as "ectopic" pulses. Each pulse, whether a sinus node pulse or an ectopic pulse has a refractory period subsequent thereto during which time the heart tissue is not responsive to any electrical pulses. A combination of sinus pulses and ectopic pulses can result in a dispersion of the refractory periods which, in turn, can trigger a tachycardia. By overdrive pacing the heart at a uniform rate, the likelihood of the occurrence of ectopic pulses is reduced and the refractory periods within the heart tissue are rendered uniform and periodic. Thus, the dispersion of refractory periods is reduced and tachycardias triggered thereby are substantially avoided. If a tachycardia nevertheless occurs, overdrive pacing at a rate faster than a tachycardia helps to eliminate ectopic pulses and reduce refractory period dispersion, and thereby helps to terminate the tachycardia.

[0005] Thus, it is desirable within patients prone to tachyarrhythmias to ensure that most beats of the heart are paced beats, as any unpaced beats may be ectopic beats. A high percentage of paced beats can be achieved simply by establishing a high overdrive pacing rate. However, a high overdrive pacing rate has disadvantages as well. For example, a high overdrive pacing rate may be unpleasant to the patient, particularly if the artificially-induced heart rate is relatively high in comparison with the heart rate that would otherwise normally occur. A high heart rate may also cause possible damage to the heart or may possibly trigger more serious dysrhythmias, such as a ventricular fibrillation.

[0006] A high overdrive pacing rate may be especially problematic in patients suffering from heart failure, particularly if the heart failure is due to an impaired diastolic function. A high overdrive pacing rate may actually exacerbate heart failure in these patients. Also, a high overdrive pacing rate may be a problem in patients with coronary artery disease because increasing the heart rate decreases diastolic time and decreases perfusion, thus intensifying ischemia. Also, the need to apply overdrive pacing pulses operates to deplete the implantable cardiac stimulation device's power supply, perhaps requiring frequent surgical replacement of the power supply. Typically, the power supply is located within the implantable cardiac stimulation device and thus this requires surgical replacement of the cardiac stimulation device.

[0007] Problems associated with overdrive pacing are particular severe for certain aggressive overdrive techniques, which trigger an increase in the pacing rate based upon detection of a single intrinsic heart beat. With such techniques, a significant increase in the pacing rate is triggered by detection of a single intrinsic heart beat so as to promptly respond to the occurrence of a high rate tachycardia, such as an SVT. As a result, even in circumstances where a high rate tachycardia has not occurred, the detection of a single intrinsic heart beat can cause a significant increase in the overdrive

pacing rate, which may be reduced only gradually. If a second intrinsic heart beat is detected before the overdrive pacing rate has been gradually lowered to a standard overdrive pacing rate, a still further increase in the pacing rate occurs. As can be appreciated, the foregoing can cause the overdrive pacing rate to increase significantly, perhaps to 150 ppm or more, even though a high rate tachycardia has not occurred.

[0008] Hence, it would be desirable to provide techniques for overdrive pacing which reduce the average overdrive pacing rate, yet still attain a sufficiently high rate to significantly reduce the likelihood of a dysrhythmia within the patient or to terminate a dysrhythmia if one nevertheless occurs. In particular, it would be highly desirable to provide overdrive pacing techniques which permit a certain percentage of paced beats (such as 90% or 95%) to be sustained by the cardiac stimulation device so as to enable the overdrive pacing rate to be minimized while still ensuring that most beats of the heart are paced beats. It is to these ends that aspects of the present invention are primarily directed.

[0009] In accordance with a first aspect of invention, a method is provided for overdrive pacing a heart using an implantable cardiac stimulation device wherein an increase in an overdrive pacing rate is performed only in response to detection of at least two intrinsic beats within a predetermined search period. Initially, an overdrive pacing rate is determined and the heart is paced at the overdrive pacing rate. Intrinsic heart beats arising during overdrive pacing are detected. If at least two intrinsic heart beats are detected within a first predetermined search period, then the overdrive pacing rate is increased by a predetermined rate increment. If at least two intrinsic heart beats are not detected within a second predetermined search period, the overdrive pacing rate is decreased by a predetermined rate of decrements. By increasing the overdrive pacing rate only in response to the detection of at least two intrinsic heart beats within the first predetermined search period, an excessively high heart rate is avoided as might otherwise occur if an overdrive pacing rate increase were based upon detection of only a single intrinsic heart beat.

[0010] In an exemplary embodiment, the first predetermined search period extends for X number of cardiac cycles following detection of a first intrinsic beat wherein X is in the range of eight to forty cycles. The second predetermined search period Z is also within the range of eight to forty cardiac cycles. If, after detection of a first intrinsic heart beat, a second heart beat is detected within X cardiac cycles, then the overdrive pacing rate is increased by Y ppm wherein Y is five, ten, fifteen, twenty or twenty-five. If Z cardiac cycles occur without a rate increase, then the rate is decremented by an amount W ppm per cardiac cycle wherein W is one, two, three, four or five.

[0011] In a second exemplary embodiment, the first predetermined search period is N consecutive cardiac

cycles, wherein N is, for example, ten. Thus, if there are at least two intrinsic heart beats within a set of N consecutive cardiac cycles, the overdrive pacing rate is increased. Otherwise, the overdrive pacing rate is decreased. With the second embodiment, it is easy to program a minimum percentage of paced beats. For example, to attain at least a minimum of 90% paced beats, N is set at ten. If fewer than 90% of the beats are paced beats (i.e., at least two beats out of every ten beats are intrinsic beats) the overdrive pacing rate is increased; otherwise it is decreased. This provides a feedback loop which maintains the pacing rate at a rate sufficient to provide about 90% paced beats on the average.

[0012] In still other embodiments, the cardiac stimulation device may periodically suspend overdrive pacing to permit a detection of three consecutive intrinsic heart beats. The intrinsic heart rate is calculated based upon those three heart beats and overdrive pacing resumes at a rate corresponding to the intrinsic heart rate. In another embodiment, the cardiac stimulation device periodically determines the intrinsic atrial rates and compares the atrial rate with the current overdrive pacing rate. If the difference between the atrial rate and the overdrive pacing rate exceeds a predetermined threshold amount, the cardiac stimulation device adjusts the overdrive pacing rate to equal the atrial rate. Otherwise, the cardiac stimulation device continues to pace at the current overdrive pacing rate.

[0013] In accordance with a second aspect of the invention, a method is provided for adaptively varying overdrive pacing characteristics so as to achieve a predetermined degree of pacing. Overdrive pacing pulses are applied to the heart in accordance with programmed values specifying overdrive pacing characteristics. An actual degree of pacing resulting from the overdrive pacing pulses is determined. The programmed values are then varied based upon the degree of pacing resulting from the overdrive pacing pulses.

[0014] In an exemplary embodiment of the second aspect of the invention, overdrive pacing is performed by periodically determining an intrinsic atrial rate, then pacing the heart at a rate equal to the intrinsic rate plus an additional overdrive pacing margin. The overdrive pacing margin is thereafter selectively increased or decreased so as to maintain the actual degree of pacing at about 95% paced beats. To this end, the overdrive pacing margin, which may initially be set to five beats per minute above the intrinsic heart rate, may be incrementally increased or decreased to maintain the percentage of paced beats at the target rate of about 95%.

[0015] In a second exemplary embodiment, overdrive pacing is performed in accordance with a dynamic atrial overdrive technique which operates to periodically increase a pacing cycle length (i.e., to decrease the pacing rate) to permit detection of intrinsic paced beats. The pacing cycle length is automatically extended every  $N_{MAX}$  cardiac cycles by a predetermined amount. Initially,  $N_{MAX}$  may be, for example, ten cycles. In accordance

with the invention, the value for  $N_{MAX}$  is periodically increased or decreased in accordance with the actual degree of pacing so as to maintain the actual degree of pacing at about 95% paced beats. Hence, possible disadvantages associated with increasing the overdrive pacing rate in response to detection of only a single intrinsic beat are substantially avoided and the average overdrive pacing rate is kept reasonably low. Other programmable values defining the dynamic atrial overdrive algorithm may also be adaptively varied in accordance with the actual degree of pacing.

[0016] Hence, with the second aspect of the invention, overdrive pacing characteristics are adaptively varied so as to reduce the average overdrive pacing rate while still maintaining, on the average, the target percentage of paced beats. The degree of risk or discomfort to the patient resulting from overdrive pacing is thereby minimised and the longevity of the power supply of the implantable medical device is increased while still achieving a sufficiently high percentage of paced beats to reduce the risk that a naturally occurring tachyarrhythmia will occur within the patient.

[0017] According to the invention there is further provided a method of controlling overdrive pacing of a patient's heart using an implantable cardiac stimulation device connected to the heart, the method comprising the steps of:

determining an overdrive pacing rate;  
overdrive pacing the heart at the overdrive pacing rate;  
detecting intrinsic heart beats arising during the overdrive pacing; and  
if at least two intrinsic heart beats are detected within a first determined search period, increasing the overdrive pacing rate by a determined rate increment; and  
if at least two intrinsic heart beats are not detected within a second determined search period, decreasing the overdrive pacing rate by a determined rate decrement.

[0018] According to the invention there is further provided a method for controlling overdrive pacing of a patient's heart using an implantable cardiac stimulation device connected to the heart, the method comprising the steps of:

determining an overdrive pacing rate;  
overdrive pacing the heart at the overdrive pacing rate;  
detecting intrinsic heart beats arising during the overdrive pacing; and  
if at least two intrinsic heart beats are detected within a first determined search period, increasing the overdrive pacing rate by a determined rate increment; and  
if no intrinsic heart beats are detected within a sec-

ond determined search period, decreasing the overdrive pacing rate by a determined rate decrement.

[0019] Preferably the first determined search period extends for a first determined number of overdrive paced cycles and preferably the first determined search period begins with a first detected intrinsic beat and preferably the first determined search period is between 8 and 40 cycles, inclusive and/or the first determined search period begins with a first paced beat and preferably the first determined search period is 10 cycles.

[0020] Preferably the second determined search period begins following an increase in the overdrive pacing rate and preferably the second determined search period is between 8 and 40 cycles, inclusive.

[0021] Preferably the determined rate increment is selected from a group including 5, 10, 15, 20 and 25 ppm and/or the determined rate decrement is selected from a group including 1, 2, 3, 4 and 5 ppm.

[0022] Preferably the step of determining the overdrive pacing rate includes the steps of:

determining a sinus rate; and  
setting the overdrive pacing rate to be equal to the sinus rate and preferably the step of determining the sinus rate includes the steps of:

detecting at least three consecutive sinus P-waves;  
determining an average interval between the P-waves; and  
calculating the sinus rate based upon the average interval and/or further including the step of periodically re-determining the overdrive pacing rate by:

suspending overdrive pacing;  
detecting at least three consecutive P-waves while overdrive pacing is suspended;  
determining an updated sinus rate based upon the at least three consecutive P-waves; and  
setting the overdrive pacing rate based upon the updated sinus rate.

[0023] Preferably the step of determining the overdrive pacing rate includes the steps of:

determining an atrial rate; and  
setting the overdrive pacing rate to be equal to the atrial rate and preferably further including the steps of:

periodically determining an updated atrial rate;  
comparing the updated atrial rate with a current overdrive pacing rate; and

if the updated atrial rate exceeds the current overdrive pacing rate by a determined amount, resetting the overdrive pacing rate to be equal to the updated atrial rate.

[0024] According to the invention there is yet further provided a method for controlling overdrive pacing of a heart using an implantable cardiac stimulation device connected to the heart, the method comprising the steps of:

programming control values specifying overdrive pacing characteristics;  
applying overdrive pacing pulses to the heart in accordance with the control values;  
determining an actual degree of pacing resulting from the overdrive pacing pulses; and  
varying the control values based on the degree of pacing resulting from the overdrive pacing pulses.

[0025] Preferably the step of programming control values specifying of overdrive pacing characteristics includes the step of selecting a parameter from a group including: an overdrive pacing rate, an overdrive pacing cycle length, a number of pacing pulses to be administered prior to a pacing cycle length extension, an amount of time prior to a pacing cycle length extension, a number of unpaced beats detected prior to a pacing cycle length extension a magnitude of rate increment, a magnitude of rate decrement, a search window duration, a pacemaker base rate, and a sensor modulated base rate.

[0026] Preferably the step of determining the actual degree of pacing resulting from the overdrive pacing pulses includes the steps of:

determining a number of paced beats occurring during a period of overdrive pacing;  
determining a number of unpaced beats occurring during the period of overdrive pacing; and  
calculating the actual degree of pacing based on a comparison of the number of paced beats and the number of unpaced beats occurring during a period of overdrive pacing and preferably the step of calculating the actual degree of pacing based on the comparison of the number of paced beats and the number of unpaced beats includes the step of determining a percentage of paced beats out of a total number of paced beats and unpaced beats.

[0027] Preferably the step of varying the control values based on the actual degree of pacing includes the steps of:

inputting a target value representative of a target degree of pacing;  
comparing the actual degree of pacing with the target degree of pacing; and

adjusting the overdrive pacing values to reduce a difference, if any, between the actual degree of pacing and the target degree of pacing and preferably the control values representative of the overdrive pacing characteristics include a pacing cycle length and a number of pacing pulses administered prior to a pacing cycle length extension; and wherein the step of applying overdrive pacing pulses to the heart in accordance with the control values includes the steps of:

counting a number of pacing pulses; and  
increasing the pacing cycle length when a count of the number of pacing pulses exceeds the parameter representative of the number of pacing pulses to be administered prior to a pacing cycle length extension and preferably the step of varying the control values includes the steps of:

increasing the number of pacing pulses to be administered prior to a pacing cycle length extension if the actual degree of pacing is less than the target degree of pacing and  
decreasing the number of pacing pulses to be administered prior to a pacing cycle length extension if the actual degree of pacing is more than the target degree of pacing.

[0028] According to the invention there is yet further provided a system for controlling overdrive pacing of a heart using an implantable cardiac stimulation device connection to the heart, said system comprising:

a receiver receiving programming values specifying overdrive pacing characteristics;  
a pulse generator generating overdrive pacing pulses for applying to the heart in accordance with the values;  
a determination unit determining an actual degree of pacing resulting from the overdrive pacing pulses; and  
an adjustment unit varying the values specifying overdrive pacing characteristics based on the degree of pacing resulting from the overdrive pacing pulses.

[0029] Apparatus embodiments of the invention are also provided. Embodiments of the invention will now be described, by way of example, with reference to the drawings, of which:

Fig. 1 is a schematic diagram illustrating a pacemaker, internally configured in accordance with the invention, and connected to a patient's heart.

Fig. 2 is a timing diagram illustrating paced beats and unpaced beats within the heart of Fig. 1.

Fig. 3 is a flow chart illustrating an overdrive pacing method wherein an overdrive pacing rate is in-

creased only if at least two intrinsic beats are detected within X cardiac cycles of one another.

Fig. 4 is a flow chart illustrating an overdrive pacing method wherein an overdrive pacing rate is increased only if at least two intrinsic heart beats are detected within a block of N consecutive cardiac cycles.

Fig. 5 is a flow chart illustrating a method for adaptively varying programmable values defining overdrive pacing characteristics so as to maintain a target degree of pacing.

FIG. 6 is a flow chart of the method of FIG. 5 configured for adaptively varying an overdrive pacing rate.

FIG. 7 is a flow chart illustrating a method for adaptively modifying the automatic pacing cycle length adjustment to maintain a target degree of pacing.

[0030] Briefly the invention relates to techniques for controlling overdrive pacing so as to achieve and maintain a target degree of pacing. The techniques will first be described with reference to FIGS. 1-4 wherein an overdrive pacing rate is increased only in response to detection of at least two intrinsic heart beats within some predetermined number of cardiac cycles. Then, techniques of the invention will be described with reference to FIGS. 5-7 wherein programmable values specifying overdrive pacing characteristics are adaptively varied so as to maintain a target percentage of paced beats.

[0031] FIG. 1 illustrates an implantable cardiac stimulating device 10 (such as a pacemaker) coupled to a patient's heart 12 by way of a ventricular lead 14 and an atrial lead 16. Ventricular lead 14 includes an electrode 18 positioned in the right ventricle 20 of the heart 12 and atrial lead 16 includes an electrode 22 positioned in the right atrium 24 of the heart 12 (preferably using a screw-in active fixation lead). Various internal components of the pacemaker operate to sense the electrical activity of the heart 12, such as the presence of P-waves and R-waves, using electrodes 18 and 22 and to selectively stimulate the heart in response to events sensed within the heart 12 by conducting electrical stimulation pulses to the heart 12 using the electrodes 18 and 22. Among other functions, the pacemaker operates to overdrive pace the heart 12 in accordance with techniques to be described below in an effort to prevent the occurrence of a tachycardia or, if a tachycardia nevertheless occurs, to terminate the tachycardia.

[0032] FIG. 2 illustrates a sequence of pacing pulses 102 administered by the cardiac stimulation device 10 of FIG. 1. Each electrical pacing pulse triggers an evoked response 104 representative of an artificially induced heart beat. Pulses 102 are administered at a constant pacing rate and, therefore, are separated by a constant pacing cycle length. FIG. 2 also illustrates a single unpaced beat 106 not preceded by a pacing pulse 102. Unpaced beat 106 may be, for example, an ectopic beat caused by a naturally occurring electrical signal generat-

ed within the heart from a location other than the sinus node from which normal sinus rhythm heart beats are naturally generated. As discussed above, ectopic beats have been found to sometimes trigger tachyarrhythmias and hence it is desirable to minimize the number of ectopic beats. Accordingly, the cardiac stimulation device 10 of FIG. 1 performs an overdrive pacing algorithm intended to generate overdrive pacing pulses 102 at a sufficiently high rate to minimize the number of unpaced beats 106 without causing an unnecessarily high heart rate. To this end, the cardiac stimulation device 10 determines the actual degree of pacing resulting from the overdrive pacing pulses and adaptively modifies the overdrive pacing rate to maintain the actual degree of pacing at about a target degree of pacing wherein about 95% of the total beats are paced beats.

[0033] FIG. 3 illustrates a technique for overdrive pacing a heart wherein an overdrive pacing rate is increased only in response to the detection of at least two intrinsic P-waves occurring within X cardiac cycles of one another wherein X is, typically, between eight and forty cardiac cycles. Briefly, the technique is summarized as follows:

1. Identify a P-wave.
2. If another P-wave occurs within X cardiac cycles, increase the pacing rate by Y bpm.
  - a) X is preferably programmable from about 8 to 40 cardiac cycles.
  - b) Y is the programmable rate increase and is preferably programmable to 5, 10, 15, 20 or 25 ppm.
3. If Z cardiac cycles occur without a pacing rate increase, then decrease the pacing rate by W ppm.
  - a) Z is the dwell time before the pacing rate is decreased and is preferably programmable from 8 to 40 cardiac cycles.
  - b) W is preferably programmable at 1, 2, 3, 4, or 5 ppm/cardiac cycle.

[0034] Additionally, the cardiac stimulation device 10 periodically suspends pacing to permit detection of three consecutive P-waves. At that time, the sinus rate is computed based upon the detected P-waves and the overdrive pacing rate is reset to be equal to the sinus rate.

[0035] This technique will now be explained more fully with reference to FIG. 3. Initially, at step 200, the intrinsic sinus rate is detected by detecting three consecutive P-waves. At step 204, a current overdrive pacing rate is set to be equal to the detected sinus rate. At step 206, the cardiac stimulation device 10 begins to count the number of paced cycles (I<sub>RESET</sub>) since the overdrive pacing rate was set based upon the intrinsic sinus rate. This count of paced cycles is eventually compared with a rate recalibration value in step 218 (described below)

and if it exceeds the recalibration value, step 200 is repeated to detect a new intrinsic sinus rate for resetting of the overdrive pacing rate.

[0036] At step 208, the atria of the heart is paced at the current overdrive pacing rate. At step 210, the number of cycles ( $I_{CYCLES}$ ) since pacing began at the current rate is counted. Note that,  $I_{RESET}$  and  $I_{CYCLES}$  are initially equal to one another. However, as will be described, the values typically diverge from one another with further execution of the method steps.  $I_{CYCLES}$  is eventually compared against a rate recovery value  $Z$  at step 214 (described below) and if  $I_{CYCLES}$  exceeds  $Z$ , the overdrive pacing rate is decreased.

[0037] At step 212, the cardiac stimulation device 10 detects any intrinsic P-waves. If a P-wave is not detected, processing proceeds to step 214 wherein the count of paced cycles since pacing began at the current rate ( $I_{CYCLES}$ ) is compared with the rate recovery value ( $Z$ ). If  $I_{CYCLES}$  exceeds  $Z$ , then step 216 is performed wherein the current overdrive pacing rate is decreased by a pacing decrement amount  $W$ , preferably preset to 1, 2, 3, 4, or 5 ppm. Processing then returns to step 206 for continued pacing at the newly reduced overdrive pacing rate. Thus, if at least  $I_{CYCLES}$  of pacing occurs before detection of a single intrinsic P-wave, the current overdrive pacing rate is reduced to provide for a rate of recovery. If, at step 214,  $I_{CYCLES}$  does not exceed  $Z$ , then step 218 is performed wherein the cardiac stimulation device 10 determines whether the count of paced cycles since the current rate was originally set ( $I_{RESET}$ ) exceeds a rate recalibration value ( $N_{RECALIBRATION}$ ). If  $I_{RESET}$  exceeds  $N_{RECALIBRATION}$ , then step 200 is again executed wherein a new sinus rate is detected and the overdrive pacing rate is reset to the new sinus rate. This ensures that the overdrive pacing rate does not remain significantly different from the sinus rate for any extended period of time. If, at step 218,  $I_{RESET}$  does not exceed  $N_{RECALIBRATION}$ , then processing returns to step 206 for additional pacing at the current overdrive pacing rate.

[0038] What has been described thus far with respect to FIG. 3 are circumstances wherein no intrinsic P-waves are detected. Steps performed in response to the detection of P-waves will now be described. More specifically, if at step 212 an intrinsic P-wave is detected, then step 220 is performed wherein a determination is made as to whether a count has already begun of the number of overdrive pacing cycles since detection of the last detected P-wave. During the first execution of step 220 following detection of the first P-wave, the count has not yet begun and hence processing continues to step 222 wherein the cardiac stimulation device 10 begins to count the number of overdrive pacing cycles since the last detected P-wave ( $I_{P-WAVE}$ ). Processing then returns to step 206 for additional pacing at the current overdrive pacing rate while incrementing  $I_{P-WAVE}$  (along with  $I_{RESET}$  and  $I_{CYCLES}$ ) with each additional pacing cycle.

[0039] If another P-wave is detected at step 212, then

execution proceeds through step 220 to step 224 wherein  $I_{P-WAVE}$  is compared with a pacing cycle increment value ( $X$ ). If  $I_{P-WAVE}$  is less than  $X$ , indicating that the last two detected intrinsic P-waves are within  $X$  cardiac cycles of one another, then step 226 is performed wherein the current overdrive pacing rate is increased by a predetermined pacing increment amount ( $Y$ ) set to, for example, 5, 10, 15, 20, or 25 ppm. Thereafter, pacing continues from step 206 at the new higher overdrive pacing rate. If, however, at step 224,  $I_{P-WAVE}$  was found to be greater than  $X$ , meaning that the last two detected intrinsic P-waves were more than  $X$  cycles apart, then the overdrive pacing rate is not immediately increased. Instead, processing proceeds to step 222 wherein  $I_{P-WAVE}$  is reset to begin a new count of the number of overdrive pacing cycles since the most recently detected P-wave.

[0040] Thus, FIG. 3 is a flow chart illustrating one technique for implementing an overdrive pacing algorithm which, among other features, (1) increases an overdrive pacing rate if two P-waves are detected within  $X$  cardiac cycles of one another, (2) decreases the overdrive pacing rate if a rate increase does not occur within at least  $Z$  cardiac cycles, and (3) resets the overdrive pacing rate to be equal to a detected sinus rate every  $N_{RECALIBRATION}$  number of cardiac cycles regardless of the extent to which the overdrive pacing rate is modified during the interim.

[0041] FIG. 4 illustrates a method for controlling overdrive pacing wherein an overdrive pacing rate is increased only if at least two intrinsic atrial beats are detected within a block of  $N$  consecutive cardiac cycles. The technique of FIG. 4 is summarized as follows:

1. At the conclusion of a block of  $N$  cardiac cycles, the cardiac stimulation device determines if there is more than one P-wave in the block of cardiac cycles. If there is more than one P-wave, the pacing rate is increased by  $Y$  ppm.

a)  $Y$  is a programmable rate increment and is preferably programmable to 5, 10, 15, 20 or 25 ppm.

2. If  $Z$  cardiac cycles occur without increasing the pacing rate, then the pacing rate is decreased by  $W$  ppm.

a)  $Z$  is the dwell time before the pacing rate is decreased and is preferably programmable from 8 to 40 cardiac cycles.

b)  $W$  is preferably programmable at 1, 2, 3, 4, or 5 ppm.

[0042] Additionally, the cardiac stimulation device 10 periodically suspends pacing to detect the intrinsic atrial rate and compare the intrinsic atrial rate with a current overdrive pacing rate. If the difference between the atrial



rate and the overdrive pacing rate exceeds a predetermined threshold ( $N_{THRESHOLD}$ ), then the overdrive pacing rate is reset to the detected atrial rate. Otherwise, overdrive pacing continues at the current pacing rate.

**[0043]** The technique will now be described in greater detail with reference to FIG. 4. Certain steps of FIG. 4 are similar to those of FIG. 3 and, accordingly, will not be re-described in detail. Initially, at steps 300 and 302, the cardiac stimulation device 10 detects the current intrinsic atrial rate and sets a current overdrive pacing rate based on the detected atrial rate. Initially, the overdrive pacing rate is set to be equal to the detected atrial rate. During subsequent iterations of steps 300 and 302, the overdrive pacing rate is set to the atrial rate only if the atrial rate minus the current overdrive pacing rate exceeds  $N_{THRESHOLD}$ .

**[0044]** At step 304, the cardiac stimulation device begins to count all paced cycles ( $I_{RESET}$ ) since the overdrive pacing rate was set at step 302. At step 305, the cardiac stimulation device 10 paces the atria at the current overdrive pacing rate while detecting any intrinsic P-waves. At step 306, all paced cycles since pacing began at the current rate are detected and counted ( $I_{CYCLES}$ ). At step 308, the cardiac stimulation device 10 also counts every group of N consecutive paced cycles ( $I_N$ ) wherein N is, for example, ten. Initially, the counts initiated at steps 302, 306 and 308 will be the same. As will be seen, however, these counts may diverge from one another with further processing of the method steps.

**[0045]** At step 310, the cardiac stimulation device 10 determines whether N pacing cycles have elapsed by examining  $I_N$ . If  $I_N$  equals N, then step 312 is performed wherein the cardiac stimulation device 10 determines whether at least two intrinsic P-waves have been detected within the group of N paced cycles. If so, the current overdrive pacing rate is increased at step 314 by an amount Y wherein Y is equal to, for example, 5, 10, 15, 20 or 25 ppm. Thereafter, processing returns to step 304 for additional atrial pacing at the new overdrive pacing rate. If, at step 312, at least two intrinsic P-waves were not detected within the group of N paced cycles, then step 316 is performed wherein the count of N paced cycles ( $I_N$ ) is reset such that the next set of N consecutive paced cycles may be counted. In this manner, the overdrive pacing rate is increased if, and only if, at least two P-waves are detected within a group of N consecutive cardiac cycles.

**[0046]** If, at step 310, N paced cycles have not yet elapsed (i.e., the count  $I_N$  is less than N), then step 318 is performed wherein the cardiac stimulation device 10 determines whether the count of paced cycles since pacing began at the current rate ( $I_{PACED}$ ) exceeds a rate recovery value (Z). If so, then at step 320, the overdrive pacing rate is decreased by a pacing decrement amount W, wherein W is preset to, for example, 1, 2, 3, 4 or 5 ppm. Hence, if the overdrive pacing rate has not been increased as a result of the detection of at least two P-waves within a block of N cycles, then the overdrive pac-

ing rate is decreased to provide rate recovery.

**[0047]** If, at step 318,  $I_{CYCLES}$  does not exceed Z, then step 322 is performed wherein the cardiac stimulation device 10 determines whether the count of paced cycles since the current rate originally set ( $I_{RESET}$ ) in step 302 exceeds a rate calibration value  $N_{RECALIBRATION}$ . If so, then steps 300 and 302 are repeated wherein overdrive pacing is suspended to permit detection of the intrinsic atrial rate and the overdrive pacing rate is then set based upon the intrinsic atrial rate. As noted above, within step 302, a determination is made as to whether the difference between the intrinsic atrial rate and the overdrive pacing rate exceeds a threshold  $N_{THRESHOLD}$  and, if not, the overdrive pacing rate is not reset to be equal to the atrial rate. If, at step 322,  $I_{RESET}$  does not exceed  $N_{RECALIBRATION}$ , then processing merely returns to step 304 for additional pacing at the current overdrive pacing rate.

**[0048]** Thus, FIG. 4 illustrates an overdrive pacing technique wherein, among other features, (1) an overdrive pacing rate is increased only if at least two P-waves are detected within a block of N consecutive cardiac cycles, (2) the overdrive pacing rate is decreased if the overdrive pacing rate is not increased within Z consecutive cardiac cycles, and (3) the overdrive pacing rate is periodically reset to an intrinsic atrial rate if the difference between the atrial rate and the current overdrive pacing rate exceeds a predetermined threshold. By increasing the overdrive pacing rate only in response to the detection of at least two P-waves within a block of N consecutive cardiac cycles, excessively aggressive overdrive pacing rate increases are avoided. Additionally, with appropriate selection of N, a minimum percentage of paced cycles can be achieved on the average. For example, by setting N equal to ten, the average percentage of paced cycles will be maintained at about 90%. If more than ten percent of the cardiac cycles are intrinsic cycles, then the overdrive pacing rate is increased. Otherwise, the overdrive pacing rate is periodically decreased. Hence, an average of about 90% is sustained.

**[0049]** With reference to FIG. 5, techniques for adaptively varying overdrive pacing characteristics are summarized. Initially, at step 400, a particular overdrive pacing technique or algorithm is selected by the cardiac stimulation device. Then, at step 401, programmable values, i.e., control values, are input from a memory 402 for control of the operation of the algorithm. (If the implantable cardiac stimulation device 10 is capable of performing only a single overdrive pacing technique, step 400 is not necessary.) Depending upon the overdrive pacing technique, the programmable values may be representative of: an overdrive pacing rate, an overdrive pacing margin, a pacing cycle length, a number of pacing pulses prior to pacing cycle length extension (Z), an amount of time prior to pacing cycle length extension, a number of unpaced beats prior to pacing cycle length extension, a rate increment magnitude (Y), a rate decrement magnitude (W), a search window duration (X), a

pacemaker base rate, and a sensor modulated base rate.

[0050] At step 403, the cardiac stimulation device 10 applies overdrive pacing pulses to the heart in accordance with the requisite programmable values. While overdrive pacing is performed, the cardiac stimulation device 10 performs steps 404-412 to adjust the programmable values so as to reduce any difference between an actual degree of pacing and a target degree of pacing. More specifically, at step 404, the cardiac stimulation device 10 determines the actual degree of pacing resulting from the pacing pulses. The actual degree of pacing may be represented by a percentage of paced beats (determined as a function of time or as a function of cardiac cycles) or by any other appropriate factor. At step 406, a target degree of pacing is input from a memory 408 and, at step 410, the cardiac stimulation device 10 compares the actual degree of pacing with the target degree of pacing. At step 412, the cardiac stimulation device 10 adjusts the values used from memory 402 so as to reduce any difference between the actual degree of pacing and the target degree of pacing. The specific adjustment depends upon a particular programmable value being adjusted. In some cases, a value may need to be increased so as to cause a decrease in the degree of pacing. In other cases, a value may need to be decreased so as to cause a decrease in the degree of pacing. The direction of the adjustment and the magnitude of the adjustment are set so as to achieve a negative feedback loop which converges the actual degree of pacing to the target degree of pacing. To this end, routine experiments are performed to determine optimal values for adjusting the various parameters to achieve the desired feedback loop and to eliminate adjustment values, if any, which may result in a positive feedback loop causing the actual degree of pacing to deviate from the target degree of pacing, rather than to converge to the target degree of pacing. The resulting adjustment in the values may be linear or nonlinear, depending upon the particular programmable values and depending upon the amount of difference, if any, between the actual degree of pacing and the target degree of pacing. As can be appreciated, a wide range of possible adjustments can be employed consistent with the invention depending upon the characteristics of the overdrive pacing technique being implemented. In many cases, two or more programmable values are adjusted simultaneously. For example, both the overdrive pacing margin and the number of pacing pulses prior to a pacing cycle length extension may be adaptively adjusted.

[0051] A first specific example of the technique of FIG. 5 will now be described with reference to FIG. 6. In this specific example, the cardiac stimulation device 10 operates to maintain the overdrive pacing rate at a rate equal to the intrinsic rate plus a programmable rate margin. The rate margin is adaptively varied so as to maintain a target degree of pacing. Initially, at step 500, the cardiac stimulation device 10 inputs an initial overdrive

pacing margin from a memory unit 502. The margin may be, for example, five beats per minute (bpm) - indicating that the heart is to be paced at a rate equal to the intrinsic heart rate plus five bpm. At step 504, the cardiac stimulation device 10 periodically determines the intrinsic heart rate and administers overdrive pacing pulses to the heart at a rate equal to the intrinsic rate plus the overdrive pacing margin. For example, if the intrinsic rate is found to be 60 bpm, the cardiac stimulation device 10 overdrive paces the heart at a rate of 65 ppm. If the intrinsic rate is found to increase to 80 bpm, then the overdrive pacing rate automatically increases to 85 ppm. In this manner, the cardiac stimulation device 10 seeks to maintain the overdrive pacing rate at a rate slightly higher than the intrinsic rate at all times.

[0052] A determination of the intrinsic rate at step 504 may be performed, for example, by periodically deactivating overdrive pacing thereby permitting detection of intrinsic beats from which the intrinsic heart rate is determined. In this regard, an estimate of the intrinsic heart rate may be calculated based upon the duration of time between the detected intrinsic beats. The greater the number of intrinsic beats that are detected, the more precise the determination of the intrinsic heart rate.

[0053] Step 506 is periodically performed wherein the cardiac stimulation device counts the number of paced beats and the number of unpaced beats until a predetermined period of time, such as 60 seconds, has elapsed. Alternatively, the cardiac stimulation device 10 counts the beats until a predetermined number of total beats, such as 100 beats, have been counted. The cardiac stimulation device 10 then calculates a percentage of the number of paced beats out of a total number of beats. In the example of FIG. 2, with nine paced beats and one unpaced beat, the percentage of paced beats is about 90%. At step 508, the cardiac stimulation device 10 inputs a target degree of pacing from a memory unit 510. The target of pacing may be, for example, 95% paced beats. At step 512, the cardiac stimulation device 10 determines whether the actual percentage of paced beats determined at step 506 is greater than the target percentage of paced beats input at step 508. If so, then step 514 is performed wherein the cardiac stimulation device 10 automatically decreases the overdrive pacing margin by a predetermined amount, such as one ppm. If not, then step 516 is performed wherein the cardiac stimulation device 10 automatically increases the overdrive pacing margin by the predetermined amount.

[0054] Thereafter, step 504 is performed using the adjusted overdrive pacing margin. Hence overdrive pacing may now occur at a rate of six ppm above the intrinsic rate or perhaps only at a rate of four ppm above the intrinsic rate. With repeated iterations of steps 504-516, the degree of overdrive pacing is thereby periodically, adaptively adjusted so as to maintain the actual percentage of paced beats at an amount about equal to the target degree of pacing, e.g., at about 95%. Hence, if the initial overdrive pacing adjustment factor was too high

such that substantially 100% of heart beats were paced beats, the overdrive pacing adjustment factor is decreased somewhat to permit occasional detection of an unpaced beat. This helps ensure that the overdrive pacing rate is not so high so as to possibly adversely affect the health of the patient. Also, avoidance of an unnecessarily high overdrive pacing rate helps preserve battery longevity. Moreover, in embodiments wherein the cardiac stimulation device relies upon detection of an occasional intrinsic beat so as to determine the intrinsic heart rate, a reduction of the overdrive pacing rate helps ensure that intrinsic beats are occasionally detected. On the other hand, if the actual degree of overdrive pacing was found to be significantly less than 95%, then the overdrive pacing rate is increased so as to prevent too many intrinsic beats from occurring which might trigger a tachyarrhythmia.

[0055] Although not specifically shown in FIG. 6, if, at step 512, the actual percentage of pacing is found to be exactly equal to the target degree of pacing, then the cardiac stimulation device 10 may be configured to not adjust the overdrive pacing adjustment factor either up or down. Also, the predetermined amount by which the overdrive pacing margin is increased may differ from that in which it is decreased. Also, the predetermined amounts may vary depending upon the current overdrive pacing rate or upon the current overdrive pacing adjustment factor. For example, if the overdrive pacing margin is currently set to 20 ppm, the factor may be increased or decreased by a greater amount than if the overdrive pacing margin was currently set to two or three ppm. Likewise, if the current overdrive pacing rate (i.e., the sum of the current intrinsic heart rate and the current overdrive pacing margin) is particularly high, then the predetermined amounts may also be relatively high. Also, note that the overdrive pacing margin may, at times, be negative. As can be appreciated, a wide range of alternatives may be provided consistent with the principles of the invention.

[0056] Another specific example of the technique of FIG. 5 will now be described with reference to FIG. 7. In this specific example, the cardiac stimulation device 10 performs a dynamic atrial overdrive technique wherein detection of a single P-wave triggers an immediate, significant increase in the overdrive pacing rate and wherein, after an increase, the pacing cycle length is periodically extended to gradually reduce the overdrive pacing rate. More specifically, the dynamic atrial overdrive technique operates as follows. The cardiac stimulation device 10 monitors the atria of the heart and detects P-waves and, in response to detection of a single P-wave, increases the overdrive pacing rate by a programmable increment value which depends upon whether the current overdrive base rate is within: 1) a lower rate overdrive (LRO) regime of between 25 and 59 ppm, 2) a middle rate overdrive regime (MRO) of between 60 and 149 ppm, or 3) an upper rate overdrive (URO) of between 150 and 185 ppm.

[0057] Within the LRO regime, the cardiac stimulation device 10 increases the overdrive pacing rate with each sensed P-wave by an LRO increment programmable value, e.g., 5, 10, 15, 20 and 25 ppm. Within the URO regime, the cardiac stimulation device 10 increases the overdrive pacing rate with each sensed P-wave by a URO increment programmable value, e.g., 5 or 10 ppm. (Typically, the LRO increment value is programmed to a high value, such as 25 ppm, whereas the URO increment is programmed to a low value such as 5 ppm.) Within the MRO regime, the cardiac stimulation device 10 increases the overdrive pacing rate with each sensed P-wave by an MRO increment which is a blended value between the LRO increment and the URO increment. The MRO increment is equal to the LRO increment when the base rate is 60 ppm. The MRO increment varies gradually when the base rate is in the range of 60 ppm to 150 ppm until the increment is equal to the URO increment when the base rate is equal to 150 ppm.

[0058] The cardiac stimulation device 10 also exploits a dynamic rate recovery technique wherein the overdrive base rate is decreased if a predetermined number of pacing cycles occur without any detected P-waves. The predetermined number of cycles and the amount of the decrease are both programmable. The amount of the decrease varies depending upon whether the base overdrive pacing rate is within one of two regimes.

[0059] The specific operation of the cardiac stimulation device 10 within the various regimes is described with reference to the following examples.

[0060] As an example of operation within the LRO regime, if the current overdrive pacing rate is 45 ppm, the LRO increment value is 5 ppm, and a P-wave is sensed, the current overdrive pacing rate is immediately increased to 50 ppm. If the P-wave arises from intrinsic atrial activity occurring at a rate of 53 bpm, then a second P-wave will be detected before a paced beat can be generated (because the overdrive base rate is still below the intrinsic rate). Hence, another P-wave is detected and the overdrive pacing rate increases to 55 ppm.

[0061] As another example of operation within the LRO regime, if the current overdrive pacing rate is 55 ppm, the LRO increment is 25 ppm, the URO increment is 5 ppm, and the patient experiences an SVT at 160 bpm, then the overdrive pacing rate increases by 25 ppm with each sensed atrial beat until the overdrive pacing rate exceeds 60 ppm. Then, any further increments begin at slightly less than the LRO increment of 25 ppm and are gradually reduced to the URO increment of 5 ppm when the overdrive pacing rate exceeds 150 ppm.

[0062] To provide rate recovery, the cardiac stimulation device 10 counts the number of pacing pulses delivered at a current overdrive pacing rate and, if the number of cycles exceeds a threshold value  $N_{MAX}$ , the cardiac stimulation device 10 decreases the overdrive pacing rate by increasing a pacing cycle length (CL) equal to the amount of time between individual pacing

pulses.  $N_{MAX}$  is preferably programmable within a range of 1 to 32 cycles. Thus, if  $N_{MAX}$  is programmed to 10 cycles and the overdrive pacing rate has remained constant for 10 cycles, then the CL is increased by a programmable rate recovery value. In this manner, so long as no intrinsic activity is detected, the overdrive pacing rate gradually decreases. Whenever intrinsic atrial activity is sensed, the counter associated with  $N_{MAX}$  is reset and, in accordance with the techniques already described, the overdrive pacing rate is incremented. Exemplary programmable CL increment values are:

Milliseconds/Cycle	
6;13	
6;19	
13;19	
19;25	

[0063] As noted, an increase in the pacing cycle length causes a corresponding decrease in the overdrive pacing rate. In the foregoing, the first value represents the increase in CL in milliseconds per cycle to be used if the current base rate is over 100 ppm. The second value represents the increase in CL in milliseconds per cycle to be used if the current base rate is 100 ppm or less. Thus, two base CL increment regimes are used. [0064] In a specific rate recovery example, if the current overdrive pacing rate is 102 ppm, the intrinsic atrial rate is 90 ppm, and the dynamic rate recovery values are programmed to 6;19 milliseconds/cycle, then the pacing cycle length decreases after every  $N_{MAX}$  as follows:

- (1) 595 milliseconds (101 ppm)
- (2) 601 milliseconds (100 ppm)
- (3) 620 milliseconds (97 ppm)
- (4) 639 milliseconds (94 ppm)
- (5) 658 milliseconds (91 ppm)

[0065] Thus, the cardiac stimulation device 10 employs a dynamic atrial overdrive technique which increases an overdrive base rate very promptly in response to detection of intrinsic atrial activity (i.e., P-waves) and provides a rate recovery technique for reducing the overdrive pacing rate when overdrive pacing is no longer needed. The degree of increment or decrement to the overdrive pacing base rate depends, as described above, upon the current base rate regime. Additional variations to the overdrive pacing rate may be based upon detection of pre-atrial contractions (PAC) or other intrinsic events.

[0066] In the technique of FIG. 7,  $N_{MAX}$  is adaptively varied to maintain a target degree of pacing. Initially, at step 600, the cardiac stimulation device 10 inputs both an initial pacing cycle length (CL) and  $N_{MAX}$  from a memory unit 602. CL may be, for example, one second (corresponding to an overdrive pacing rate of 60 ppm) and

$N_{MAX}$  may be, for example, initially set to ten.

[0067] At step 604, the cardiac stimulation device 10 repeatedly administers overdrive pacing pulses to the heart in accordance with the dynamic atrial overdrive algorithm described above wherein the CL is automatically extended every  $N_{MAX}$  pulses to allow occasional detection of intrinsic heart beats or other intrinsic activity. While step 604 is performed, the cardiac stimulation device 10 additionally performs steps 605-616 as follows.

10 The cardiac stimulation device counts the number of paced beats and unpaced beats for either a predetermined period of time or a predetermined number of pulses then calculates the percentage of paced beats at step 606. A target degree of pacing is input at step 608 from a memory 610 and, at step 612, the cardiac stimulation device 10 determines whether the actual percentage of pacing is greater than the target percentage of pacing. If so, then  $N_{MAX}$  is decreased by a predetermined amount, such as one cycle, at step 614. If not, then  $N_{MAX}$  is increased by a predetermined amount, such as one cycle, at step 616. Thereafter, the overdrive pacing performed by the cardiac stimulation device 10 during step 604 is performed using the adjusted value for  $N_{MAX}$ . With repeated iterations of steps 604-616, the actual degree of pacing is maintained substantially at or near the target degree of pacing so as to prevent excessive overdrive pacing while still minimizing the number of non-paced beats. In this regard,  $N_{MAX}$  is decreased when the actual percentage of pacing is greater than the target percentage of pacing so as to permit a more prompt detection of an intrinsic pulse from which a new intrinsic heart rate is determined. By permitting a more prompt detection of a next intrinsic beat, the overdrive pacing rate can thereby be adjusted in accordance with the dynamic atrial overdrive algorithm to more closely match the intrinsic rate. In contrast, by increasing  $N_{MAX}$  if the actual percentage of pacing is found to be less than 95%, a greater amount of time elapses prior to detection of a next intrinsic pulse, thereby delaying readjustment of the overdrive pacing rate. This may result in a generally higher overdrive pacing rate. In any case, regardless of whether the adjustments to  $N_{MAX}$  result in an increase or decrease in the overall average overdrive pacing rate, the adjustments to  $N_{MAX}$  will typically operate to maintain the percentage of paced beats at about the target percentage and the advantages set forth above are achieved.

[0068] In another specific example of the technique of FIG. 5, the implantable cardiac stimulation device 10 employs a technique for modulating the base rate of the cardiac stimulation device 10 based upon circadian rhythms of the patient. The technique for modulating the base rate is described in U.S. Patent No. 5,476,483 to Bornzin *et al.* which is incorporated by reference herein. Briefly, in accordance with the technique of the Bornzin *et al.* patent, the base rate associated with a transfer function of a rate-responsive cardiac pacemaker is modulated. Activity sensor measurements are used to derive

activity variance measurements, which in turn are used to modulate the base pacing rate. In one embodiment, a histogram is used to store activity variance measurements collected over a period of about one week. A histogram is used to derive an activity variance threshold, which is compared to current activity variance measurements to determine if the patient is asleep. If the patient is deemed to be asleep, the pacing rate is set to a rate that comfortably meets the low metabolic demands of the patient during sleep. In alternative embodiments, the activity variance measurements are applied to a base rate slope to modulate the base pacing rate.

[0069] Thus, the base rate can be modulated and as such, the percentage of time that underlying, intrinsic P-waves are detectable during a search period can be adjusted by adaptively adjusting the base rate in accordance with the adaptive techniques described above. With proper selection of appropriate adaptive adjustment values (when the cardiac stimulation device extends an atrial escape interval to permit detection of an underlying, intrinsic P-wave), the adjusted base rate will limit the extension of the escape interval so that the base rate is in fact higher than the underlying atrial rate. Accordingly, there will be few, if any, emerging P-waves. More specifically, parameters sleep\_rate and BPR\_slope within Equation 9 of the *Bornzin et al.* patent are adaptively adjusted so as to achieve a target degree of pacing. Increasing sleep\_rate and BPR\_slope has the effect of increasing the base rate and thus increasing the percentage of atrial pacing.

[0070] What has been described are various techniques for overdrive pacing including techniques for adaptively adjusting overdrive pacing programmable values so as to maintain a desired or target degree of overdrive pacing, or to maintain any other desirable characteristic of the overdrive pacing. The overdrive pacing techniques have been described primarily with reference to flow charts illustrating steps performed by components of an implantable cardiac stimulating device. Each method step of the flow charts additionally represents a functional component for performing the method step. The functional component may comprise individual hardware devices or may comprise software components. In some cases a single functional component will perform two or more method steps. In other cases two or more functional components in combination will perform a single method step. In general, the techniques described herein may be implemented using any appropriate technology such as hardware, software, firmware, or the like.

#### Claims

1. A system for controlling overdrive pacing of a heart using an implantable cardiac stimulation device configured for connection to a patient's heart, the system comprising:

means for determining an overdrive pacing rate;

means for overdrive pacing the heart at the overdrive pacing rate;

means for detecting intrinsic heart beats arising during the overdrive pacing;

means, responsive to detection of at least two intrinsic heart beats within a first determined search period, for increasing the overdrive pacing rate by a determined rate increment; and

means, responsive to detection of no more than one intrinsic heart beat within a second determined search period, for decreasing the overdrive pacing rate by a determined rate decrement.

2. A system for controlling overdrive pacing of a patient's heart using an implantable cardiac stimulation device connected to the heart, the system comprising:

a determination unit determining an overdrive pacing rate;

an overdrive pacing unit for overdrive pacing the patient's heart at the overdrive pacing rate;

a detection unit for detecting intrinsic heart beats arising during the overdrive pacing;

an overdrive pacing rate increment unit for increasing the overdrive pacing rate by a determined rate increment in response to detection of at least two intrinsic heart beats within a first determined search period; and

an overdrive pacing rate decrement unit for decreasing the overdrive pacing rate by a determined rate decrement in response to detection of no more than one intrinsic heart beat within a second determined search period.

3. The system of claim 1 or claim 2 wherein the first determined search period extends for a first determined number of overdrive paced cycles.
4. The system of claim 3 wherein the first determined search period begins with a first detected intrinsic beat and preferably the first determined search period is between 8 and 40 cycles, inclusive.
5. The system of claim 3 wherein the first determined search period begins with a first paced beat and preferably wherein the first determined search period is 10 cycles.
6. The system of claim 1 or 2 wherein the second determined search period begins following an increase in the overdrive pacing rate and preferably wherein the second determined search period is between 8 and 40 cycles, inclusive.

7. The system of claim 1 or 2 wherein the determined rate increment is selected from a group including 5, 10, 15, 20 and 25 ppm and/or wherein the determined rate decrement is selected from a group including 1, 2, 3, 4 and 5 ppm. 5
8. The system of claim 1 or 2 wherein the means for determining the overdrive pacing rate includes:
- means for determining a sinus rate; and 10
  - means for setting the overdrive pacing rate to be equal to the sinus rate.
9. The system of claim 8 wherein the means for determining the sinus rate is arranged to:
- detect at least three consecutive sinus P-waves; 15
  - determine an average interval between the P-waves; and
  - calculate the sinus rate based upon the average interval. 20
10. The system of claim 8 further including the step of periodically redetermining the overdrive pacing rate by: 25
- suspending overdrive pacing;
  - detecting at least three consecutive P-waves while overdrive pacing is suspended; 30
  - determining the updated sinus rate based upon the at least three consecutive P-waves; and
  - setting the overdrive pacing rate based upon the updated sinus rate. 35
11. The system of claim 1 or 2 wherein the means for determining the overdrive pacing rate includes: 40
- means for determining an atrial rate and
  - means for setting the overdrive pacing rate to be equal to the atrial rate and preferably wherein the means for determining an atrial rate is arranged to:
- periodically determine an updated atrial rate; 45
  - compare the updated atrial rate with a current overdrive pacing rate; and
  - if the updated atrial rate exceeds the current overdrive pacing rate by a determined amount, reset the overdrive pacing rate to be equal to the updated atrial rate. 50
12. A system for controlling overdrive pacing of a heart using an implantable cardiac stimulation device configured for connection to a patient's heart, the system comprising: 55
- means for receiving programming control values specifying overdrive pacing characteristics;
  - means for generating overdrive pacing pulses for applying to the patient's heart in accordance with the control values;
  - means for determining an actual degree of pacing resulting from the overdrive pacing pulses; and
  - means for varying the control values based on the degree of pacing resulting from the overdrive pacing pulses.
13. A system as claimed in claim 12 in which the means for receiving programming control values receives a parameter selected from a group including an overdrive pacing rate, an overdrive pacing cycle length, a number of pacing pulses to be administered prior to a pacing cycle length extension, an amount of time prior to a pacing cycle length extension, a number of unpaced beats detected prior to a pacing cycle length extension, a magnitude of rate increment, a magnitude of rate decrement, a search window duration, a pacemaker base rate, and a sensor modulated base rate.
14. A system as claimed in claim 12 in which the means for determining an actual degree of pacing resulting from the overdrive pacing pulses includes:
- means for determining the number of paced beats occurring during a period of overdrive pacing;
  - means for determining a number of unpaced beats occurring during the period of overdrive pacing; and
  - means for calculating the actual degree of pacing based on a comparison of the number of paced beats and the number of unpaced beats occurring during a period of overdrive pacing and preferably the means for calculating is arranged to determine a percentage of paced beats out of a total number of paced beats and unpaced beats.
15. A system as claimed in claim 12 in which the means for varying the control values based on the actual degree of pacing includes:
- means for inputting a target value representative of a target degree of pacing;
  - means for comparing the actual degree of pacing with the target degree of pacing; and
  - means for adjusting the overdrive pacing values to reduce a difference, if any, between the actual degree of pacing and the target degree of pacing, and preferably wherein the control values representative of the overdrive pacing

characteristics include a pacing cycle length and a number of pacing pulses administered prior to a pacing cycle length extension; and wherein the means for generating overdrive pacing pulses includes:

5

means for counting a number of pacing pulses; and

means for increasing the pacing cycle length when a count of the number of pacing pulses exceeds the parameter representative of the number of pacing pulses to be administered prior to a pacing cycle length extension, and preferably wherein the means for varying the control values includes:

10

15

means for increasing the number of pacing pulses to be administered prior to a pacing cycle length extension if the actual degree of pacing is less than the target degree of pacing; and means for decreasing the number of pacing pulses to be administered prior to a pacing cycle length extension if the actual degree of pacing is more than the target degree of pacing.

20

25

16. An implantable cardiac stimulation device including means for determining an overdrive pacing rate;

30

a pulse generator generating overdrive pacing pulses for applying to the heart at the overdrive pacing rate; and

means for detecting intrinsic heart beats arising during the overdrive pacing in which the means for determining an overdrive pacing rate are arranged to increase the overdrive pacing rate by a determined rate increment if at least two intrinsic heart beats are detected within a first determined search period by the means for detecting intrinsic heart beats, and the means for determining an overdrive pacing rate are arranged to decrease the overdrive pacing rate by a determined rate decrement if at least two intrinsic heart beats are not detected or alternatively no intrinsic heart beats are detected within a second determined search period by the means for detecting intrinsic heart beats.

35

40

45

50

55

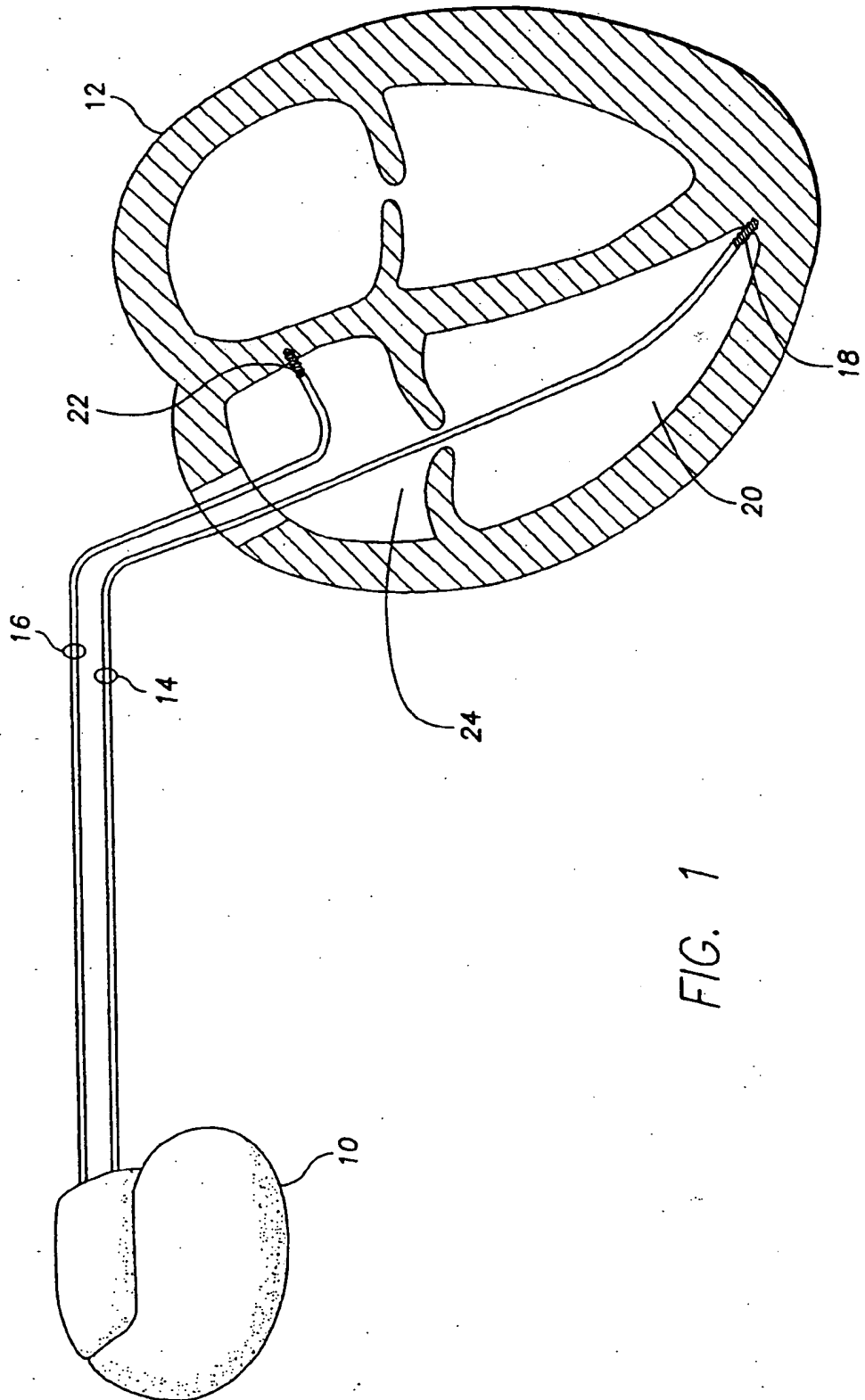
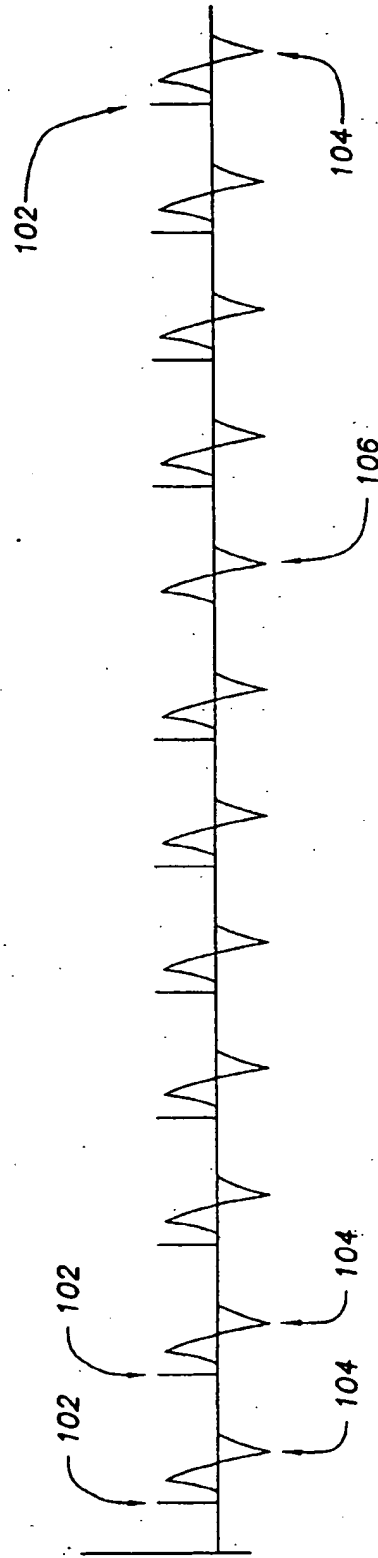


FIG. 1



FIG. 2



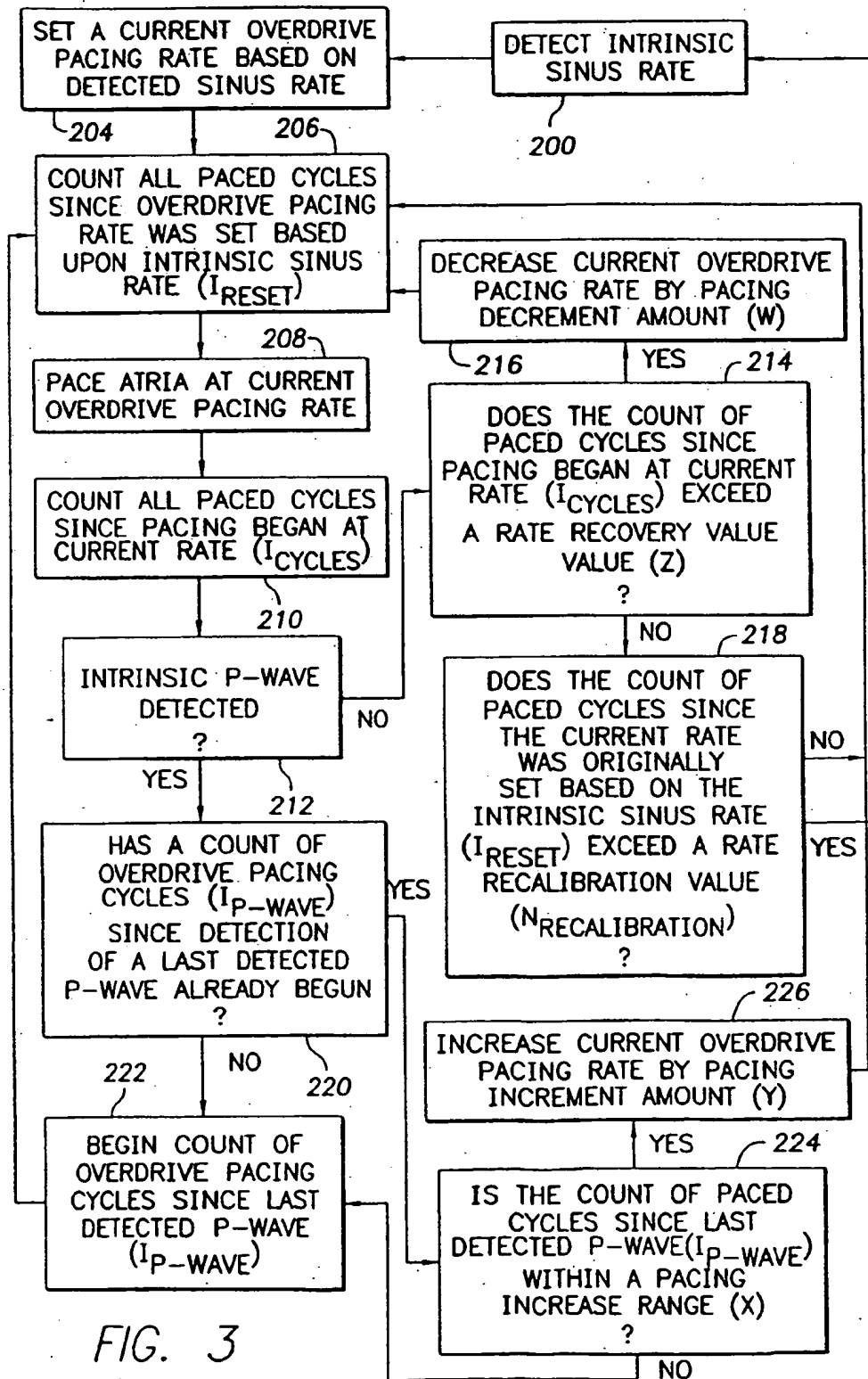
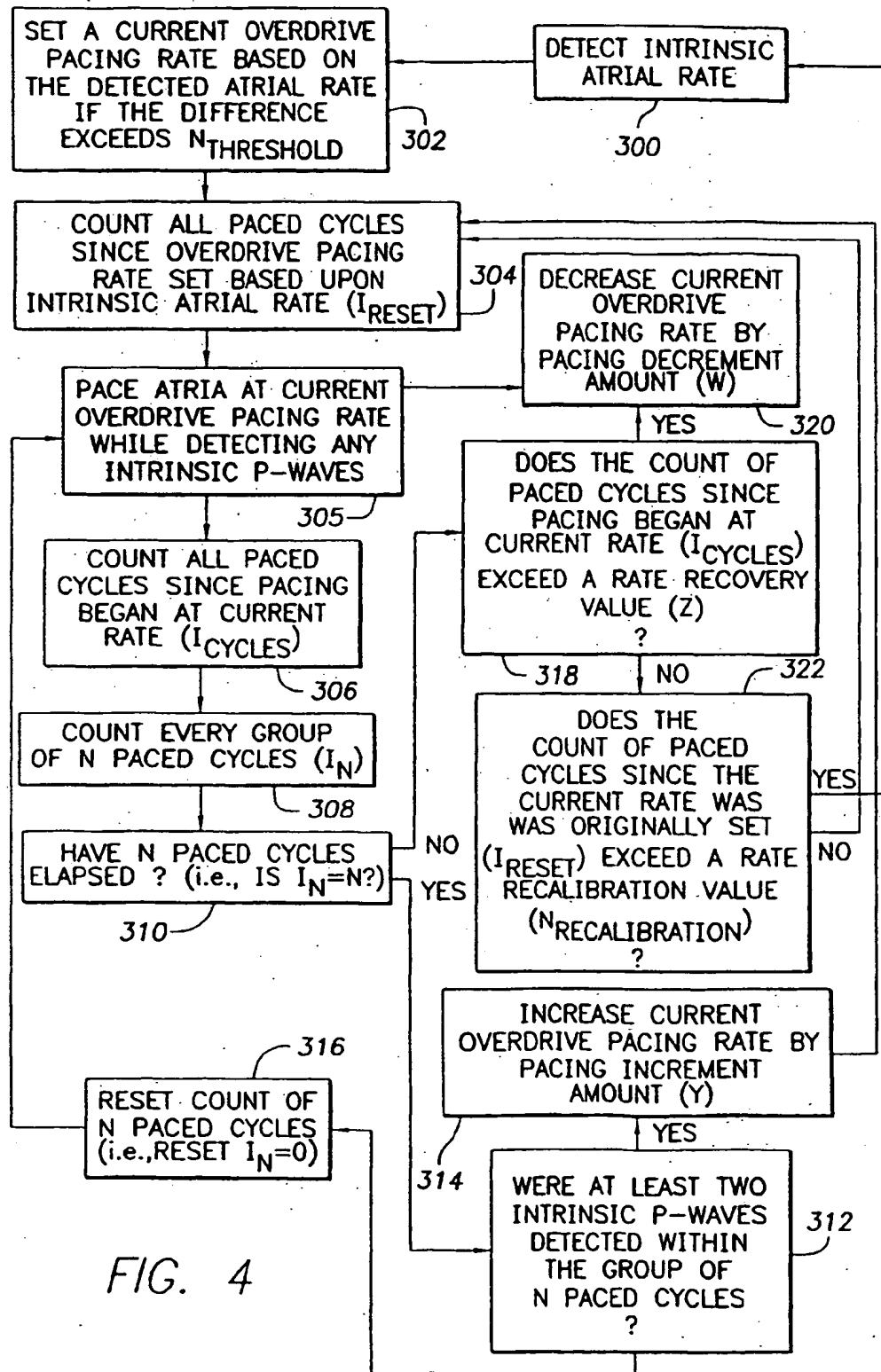


FIG. 3



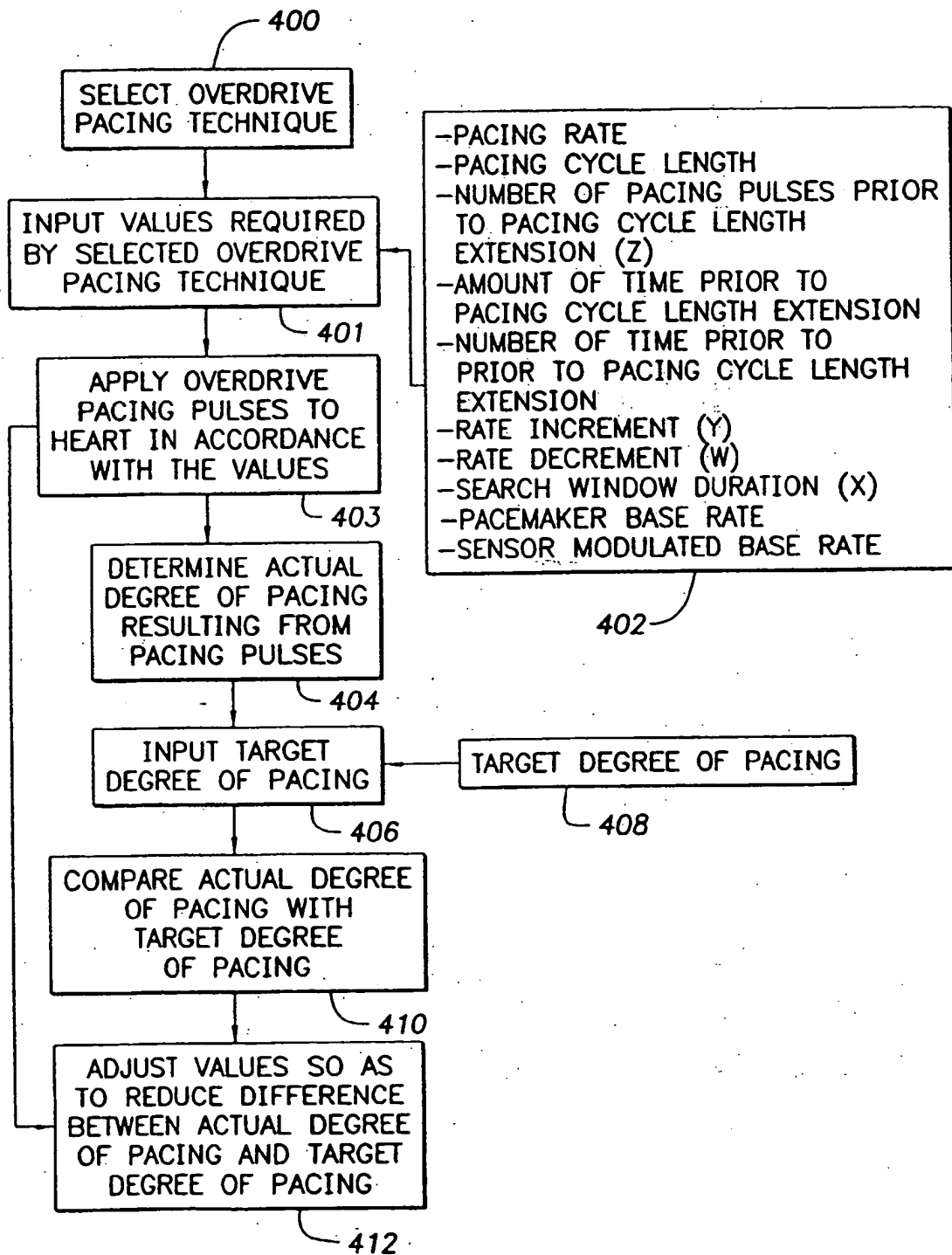


FIG. 5

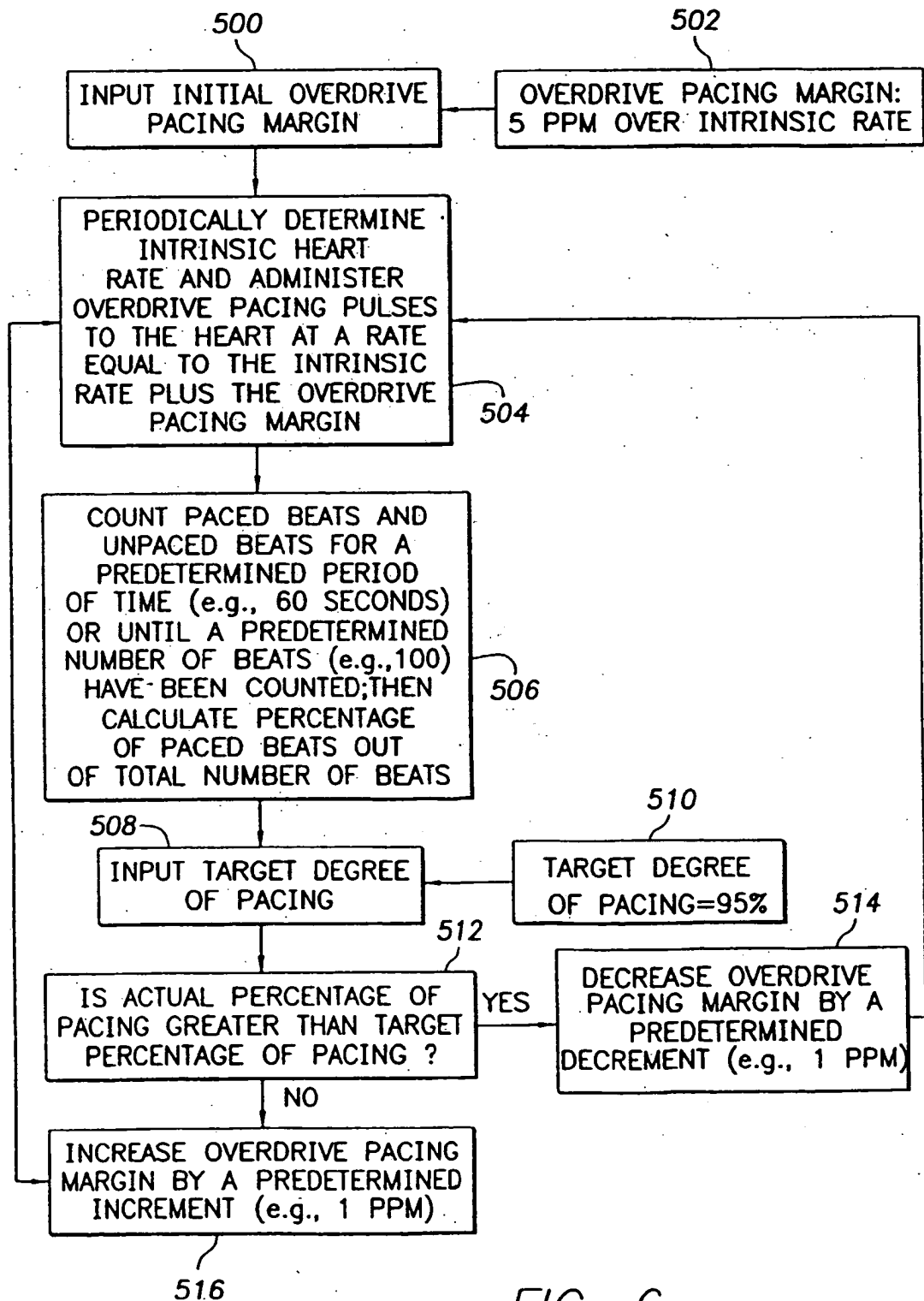


FIG. 6

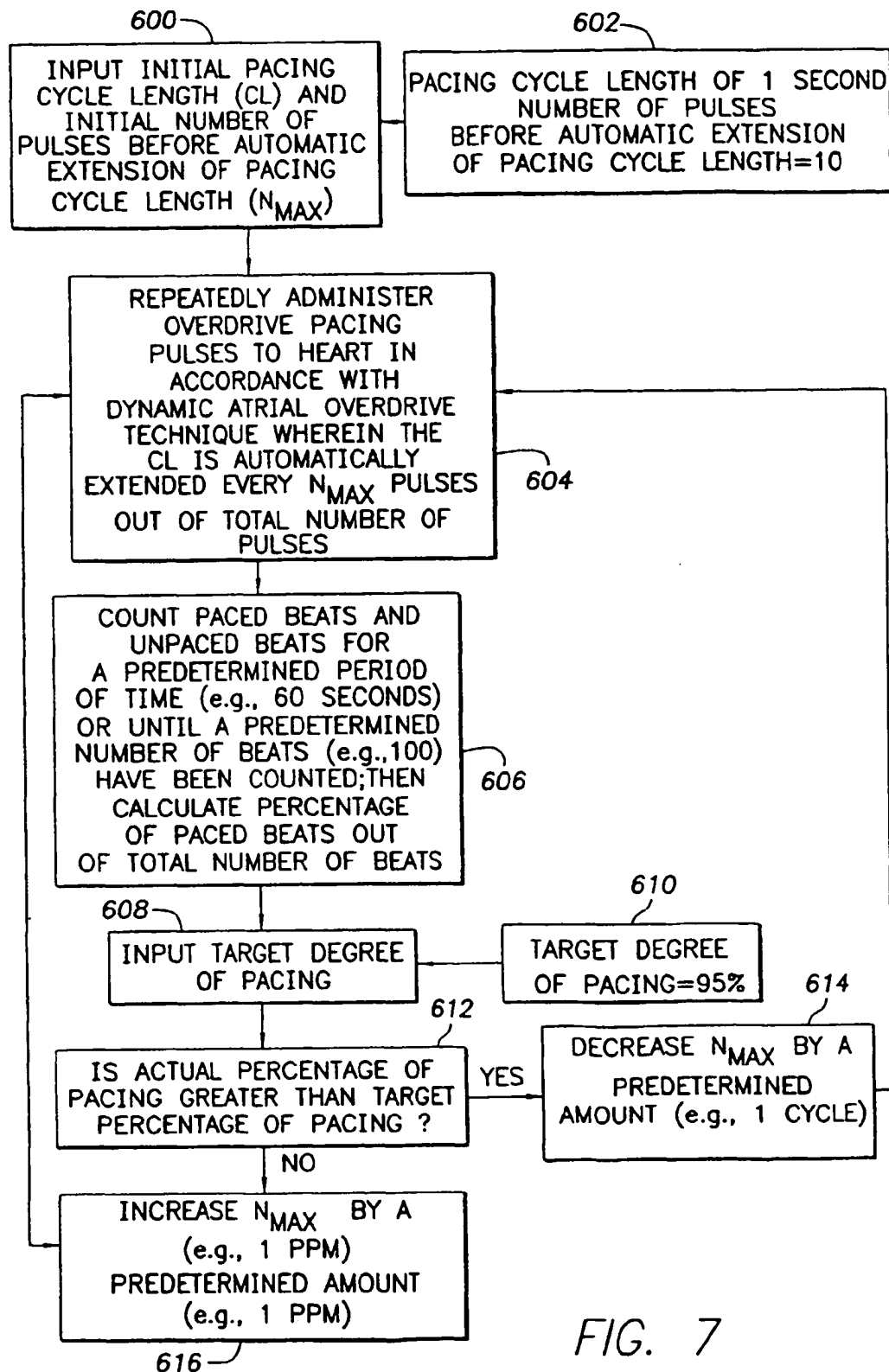


FIG. 7